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## Proposed Examiner's Amendment

### Draft

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 06-8 and 11 May 2009 with Ms. Alicia Mills, Applicants' Representative.

#### **In the Claims**

Please amend the Claims as follows:

Listing of Claims:

1. (Currently Amended) A method effective to protect one or more properties of a biological material or device containing said biological material during the process of sterilization which comprises:
  - a) packaging the biological material;
  - b) providing a protective atmosphere within the package, wherein providing a protective atmosphere within the ~~package~~ packaging of the packaged biological material is carried out by: ~~at least partially~~ removing an original atmosphere under vacuum [[,]] and replacing the original atmosphere, wherein removing and replacing is done by evacuating and backfilling the original atmosphere in the package, flushing the original atmosphere in the package, or substituting the original atmosphere in the package, and wherein replacing the original atmosphere is done with a protective atmosphere comprising a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere;
  - c) sterilizing the packaged biological material or device containing said biological material in the presence of said protective atmosphere to reduce and/or inactivate an adventitious agent or adventitious agents.

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2-31 (Canceled)

32. (Currently Amended) The method of claim 1, wherein the inert atmosphere comprises ~~at least one inert gas selected from the group consisting of nitrogen and argon.~~

33. (Currently Amended) The method of Claim 1, wherein the reducing atmosphere comprises at least one reducing gas selected from the group consisting of hydrogen ~~[[,]]~~ and hydrogen sulfide ~~and carbon monoxide.~~

34. (Currently Amended) The method of Claim 1, wherein the mixture of inert atmosphere and reducing atmosphere contains from about 5 to about 30% ~~0.5 to about 99%~~ by volume reducing atmosphere gas.

35. (Currently Amended) The method of Claim 1, wherein the original atmosphere is ~~at least partially~~ removed under a vacuum of from about 1 to about 200 torr.

36-51 (Canceled)

52. (Previously Presented) The method of Claim 1, wherein the biological material is bone.

53-63 (Canceled)

64. (Currently Amended) The method of Claim 1, wherein the biological material is selected from the group consisting of food, tissue and therapeutically useful substance ~~and therapeutically useful device.~~

65-88 (Canceled)

89. (new) the method of claim 1, wherein the inert atmosphere comprises argon.

90. (New) The method of Claim 1, wherein the inert atmosphere comprises helium.

91, (New) The method of Claim 1, wherein the inert atmosphere comprises neon.

92, (New) The method of Claim 1, wherein the inert atmosphere comprises krypton.

93. (New) The method of Claim 1, wherein the inert atmosphere comprises xenon.

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94. (New) The method of Claim 1, wherein the inert atmosphere comprises carbon dioxide.
95. (New) The method of claim 1, wherein removing and replacing is done by removing an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.
96. (New) The method of claim 1, wherein removing and replacing is done by evacuating an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.
97. (New) The method of claim 1, wherein removing and replacing is done by substituting an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.
98. (New) The method of claim 1, wherein removing and replacing is done by flushing an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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11 May 2009